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ART UNIT	**PAPER NUMBER**
1646	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/827,937	Applicant(s) Li et al
	Examiner Nirmal S. Basi	Art Unit 1646

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 21, 2001*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *23-78* is/are pending in the application.

4a) Of the above, claim(s) *75-78* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *23-74* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The Amendment filed 8/8/01 (paper number 3) has been entered.

2. ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 23-74, drawn to antibody which specifically binds to the polypeptide of SEQ ID NO:2, antibody which specifically binds to the polypeptide encoded by human cDNA in ATCC Deposit No:209003 and method for the production of said antibody, classified in class 530, subclass 387.9, for example.

II. Claims 75-78, drawn to a method for screening a compound which binds to a polypeptide comprising amino acids 2-342 of SEQ ID NO:2 and screening a compound which binds to a polypeptide encoded by human cDNA in ATCC Deposit No:209003 , classified in class 435, subclass 7.1 for example.

The inventions are distinct, each from the other because of the following reasons:

The antibody of Invention I are distinct from the methods of Invention II wherein the antibody of Invention I can neither be used in nor made by the methods of Invention II.

The methods of Inventions I and II are distinct from each other because they are independent, using separate method steps, active agents and having different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. A search of the art for Inventions I and II would not be co-extensive with each other. Because the searches required

for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner.

During a telephone conversation with Elizabeth Haanes 1/24/03 a provisional election was made without to prosecute the invention of Group I, claims 23-74. Affirmation of this election must be made by applicant in responding to this Office action. Claims 75-78 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

3. The disclosure is objected to because of the following informalities:

Applicants are required to use the heading "BRIEF DESCRIPTION OF THE DRAWINGS". See MPEP 608.01(f). On page 6, Applicant has written ""BRIEF DESCRIPTION OF THE FIGURES".

Appropriate correction is required.

4. The disclosure is objected to because of the following informalities:

Applicant has disclosed that clone 209004 was deposited but has not indicated the address of where it was deposited (see page 8). The specification should be amended to reflect the correct address for the ATCC and deposit information.

Further, the claims require availability of the clone 209003 indicated as deposited with ATCC. Applicant must provide evidence that clones listed in instant application will be available under the criteria (I)-(V) listed below. Although, the aforementioned cDNA if available today from ATCC, may not be available in the future. An enabled ATCC deposit would satisfy the requirements of 35 USC §112, first paragraph.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(I) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(II) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

(III) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(IV) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(V) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

Claim Rejection, 35 U.S.C. 112

5. Claims 39, 50, 65, 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 is indefinite because it is unclear what immunogen is introduced into an animal to produce the antibody of claim 23. The term "immunogen" carries no weight in terms of structure and function and encompasses an unlimited number of alterations and reads on unrelated molecules.

Claims 50 is indefinite because it is unclear what is immunogen is introduced into an animal to produce the antibody fragment of claim 40. The term "immunogen" carries no weight in terms of structure and function and encompasses an unlimited number of alterations and reads on unrelated molecules.

Claims 65 is indefinite because it is unclear what is immunogen is introduced into an animal to produce the antibody fragment of claim 51. The term "immunogen" carries no weight in terms of structure and function and encompasses an unlimited number of alterations and reads on unrelated molecules.

Claims 74 is indefinite because it is unclear what is immunogen is introduced into an animal to produce the antibody fragment of claim 66. The term "immunogen" carries no weight in terms of structure and function and encompasses an unlimited number of alterations and reads on unrelated molecules.

Claim 50 is indefinite because the method steps do not achieve the goal of preparing a n antibody fragment as stated in the preamble. An acceptable method claim must contain three sections: 1) a preamble, 2) method steps that clearly define what is to be done in each step, and 3) a conclusion that what was stated in the preamble was achieved. The method of claim 50, method of preparing an antibody fragment, contains the same steps as those used to produce an intact antibody, as claimed in claim 39, but with the outcome the fragment is isolated. It is not clear that the fragments to which applicant refers are naturally produced and recoverable. It is suggested the applicant include additional method steps disclosing the production of the antibody fragments and how they are recovered.

Claim 74 is indefinite because the method steps do not achieve the goal of preparing a n antibody fragment as stated in the preamble. An acceptable method claim must contain three

sections: 1) a preamble, 2) method steps that clearly define what is to be done in each step, and 3) a conclusion that what was stated in the preamble was achieved. The method of claim 74, method of preparing an antibody fragment, contains the same steps as those used to produce an intact antibody, as claimed in claim 65, but with the outcome the fragment is isolated. It is not clear that the fragments to which applicant refers are naturally produced and recoverable. It is suggested the applicant include additional method steps disclosing the production of the antibody fragments and how they are recovered.

Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st paragraph

The following is a quotation of 35 U.S.C. 101:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23-74 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to an isolated antibody/antibody fragment:

A) which specifically binds to the polypeptide of amino acids 1-342 or 2-342 of SEQ ID NO:2

B) which specifically binds to the polypeptide encoded by the human cDNA in ATCC deposit NO.209003, (ii) which specifically binds to the mature polypeptide polynucleotide produced upon cellular expression of the polypeptide encoded by the human cDNA in ATCC Deposit NO:209003.

Further, claim are drawn to method of producing isolated antibody and antibody fragments.

A "specific utility" is a utility that is specific to the subject matter claimed, as opposed to a "general utility" that would be applicable to the broad class of the invention. A "substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. A "well established utility" is a utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. A "well established utility" must also be specific and substantial as well as credible.

Based on the record, there is not a "well established utility" for the claimed invention. Applicant has asserted utilities for the specifically claimed invention of claims 23-74. The utilities disclosed in the specification are based on methods using the claimed antibody to specifically bind to polypeptide disclosed in SEQ ID NO:2. The antibody may be used for treatment in receptor-mediated and related disorders, drug-screening methods using receptor polypeptides or in assays for detecting polypeptide disclosed in SEQ ID NO:2. The specification discloses:

a) EBV-induced G-protein coupled receptor of the present invention disclosed in SEQ ID NO:2 (EBI-2) has about 25% identity and 49% similarity to the EBI-1 gene over an approximately 350 amino acid stretch, page 7. EDG-2 (G protein coupled receptor of SEQ ID NO:4) has about 54% identity and 73% similarity to the EDG-1 orphan G-protein coupled receptor, page 7. Both EBI-1 and EDG-1 are found in a variety of tissue and are themselves considered orphan receptors.

In light of the specification the skilled artisan can speculate that EBI-2 receptor is a seven transmembrane protein belonging to the G-protein coupled receptor super family. However, no disclosure is provided within the instant specification on what specific function a putative EBI-2 receptor protein possesses, or how to specifically assay for such, ligands that bind, promoters that activate, nor are any disease states disclosed that are directly related to EBI-2 receptor dysfunction. There is no disclosure in the specification of ligands that bind to EBI-2 receptor. Mudroch et al (Ref. A) discloses, the superfamily of G-protein-coupled receptors are highly divergent in their effects and include receptors for hormones, neurotransmitters, paracrine substances, inflammatory mediators, certain proteinases, taste and odorant molecules, and even photons and calcium ions (page 3032, introduction). Members of a sub-family of G-protein-coupled receptors are also highly divergent in their effects, as highlighted by Mudroch et al, in the discussion of cytokine G-protein-coupled receptors (see pages 3032-3039). The utility of EBI-2 G-protein coupled receptor cannot be implicated solely from homology to known G-protein coupled receptors because the art does not provide teaching stating that all members of a sub-family of G-protein coupled receptors must have the same effects, the same ligands and be involved in the same disease states, the art discloses

evidence to the contrary. For example, Mudroch et al discloses even though CCR6 is a member of the chemokine G-protein coupled receptors family and IL-2 was shown to up-regulate CCR6 mRNA recent data contradict this finding, and as a consequence, the effect of IL-2 on CCR6 expression remains uncertain (page 3035, second column, first paragraph). Further, the unpredictability of determining the G-protein associated with specific G-protein coupled receptors is highlighted by Watson et al (Ref B, page 5, third paragraph), who disclose,"Site directed mutagenesis, deletions and chimeric receptor studies have been used in an attempt to identify the region of the β2 adreoceptor that couples with Gs. This work has highlighted a sequence of ~8 amino acids in the N-terminal and ~12 amino acids in the C-terminus of the third transmembrane loop as important determinants of this interaction. However, it appears that additional regions of the receptor also participate in the binding to the G-protein, most notably in the second intracellular loop, and that it is the overall 3-dimensional structure of the receptor on the cytoplasmic side of the membrane that is important for the interaction with G-protein. It has therefore not been possible to identify consensus amino acid sequences that confer G-protein specificity, and thus G-protein interactions cannot be predicted from the primary amino acid sequence", (Ref B, page 5, third paragraph). Therefore the disclosure of Watson predicts, using the primary structure of the G-protein coupled receptor the skilled artisan cannot predict its associated G-protein. The EBI-2 receptor of instant invention is considered by the examiner to be a member of the orphan receptor of G-protein coupled receptors i.e. seven transmembrane receptor with no known endogenous ligands. Watson et al devote a whole chapter to orphan G-protein coupled receptors and group them separately because even though the orphan

receptors posses a certain degree of homology to G-protein coupled with known function, the orphan receptors require further research before they can be classified into one of the groupings of known G-protein coupled receptors (Ref B, pages 223-230). Further, a position that the EBI-2 receptor is related to EBI-1, and therefore must have the same biological activity and be classified as EBI-1 type receptor, can not be made, without the knowledge of the endogenous ligand for EBI-2 receptor. The specification compares EBI-2 receptor to EBI-1 receptor, which itself is an orphan receptor without a function. The assumption that an orphan receptor be placed in a particular group is not always true as highlighted by the statement Watson, who states, "It was originally claimed that the human homologue of RDC1 codes for VIP receptor, but this is no longer thought to be correct" (Ref B, page 228). Therefore, since neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the claimed EBI-2 receptor and fragments thereof, further experimentation is necessary to attribute a utility to the claimed polypeptides and fragments thereof.

The instant application does not disclose the biological role of EBI-2 receptor or its significance. The utilities are not considered to be specific and substantial because the specification fails to disclose any particular function or biological significance for the EBI-2 receptor of the instant invention. The disclosed protein, whose cDNA has been isolated, is said to have a potential function based upon its amino acid sequence similarity to other known proteins. After further research, a specific and substantial credible utility might be found for the claimed isolated compositions. This

further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

Claims of instant invention are drawn to an antibody that binds to a protein with, as yet, undetermined function or biological significance. Because the protein of SEQ ID NO:2 lacks utility, the antibody which binds SEQ ID NO:2, also lacks utility. Further, since the antibody lacks utility the method for its production also lacks utility. There is no evidence of record or any line of reasoning that would support a conclusion that the claimed antibody of the instant application or the protein disclosed in SEQ ID NO:2 was, as of the filing date, useful for diagnosis, prevention, and

treatment of disease, such as cancers etc. Until some actual and specific significance can be attributed to the protein identified in the specification as EBI-2 receptor, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility as of the filing date.

The protein disclosed in SEQ ID NO:2 is a compounds which share some structural similarity to receptor proteins having GPCR domains based on sequence similarity. As disclosed by the specification, the family of proteins related to EBI-2 receptor may have diverse effects and bind a diverse number of ligands. The family of proteins having GPCR like domains have different levels of expression, and play roles in the pathogenesis of various diseases. Although the family of receptor proteins having EBI-2 receptor like domains may share some common structural motifs, various members of the family may have different sites of action and different biological effects. In the absence of knowledge of the ligand for EBI-2 receptor or the biological significance of this protein, there is no immediately evident patentable use for the antibodies that bind said receptor. To employ a protein of the instant invention in any of the disclosed methods would clearly be using it as the object of further research. Such a use has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for EBI-2 receptor then the claimed invention as disclosed does not meet the requirements of 35 U.S.C. §101 as being useful.

In conclusion, the utilities asserted by Applicant are not specific or substantial. Since no specific function of the polypeptide of instant invention is known, and the hypothesized function is based entirely on conjecture from homologous polypeptides, the asserted utilities are not specific to instant polypeptide, but rather are based on family attributes. Neither the specification nor the art of record disclose the protein of SEQ ID NO:1 or fragments thereof useful to identify drugs that affect said protein and modulate its activity. Similarly, neither the specification nor the art of record disclose any instances where disorders can be effected by interfering with the activity using the EBI-2 receptor or fragments thereof. Thus the corresponding asserted utilities for the claimed antibody are essentially methods of using said antibody to bind to EBI-2 receptor.. Therefore the asserted utilities are essentially methods of testing for or for potentially treating unspecified, undisclosed diseases or conditions, which does not define a "real world" context of use. Treating or testing for compounds that interact with EBI-2 receptor which may be implicated in an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the claimed EBI-2 receptor and fragments thereof, further experimentation is necessary to attribute a utility to the claimed polypeptides and fragments thereof. See Brenner v. Manson, 383 U.S. 519, 535–36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting

license. It is not a reward for the search, but compensation for its successful conclusion."). Further since the nucleic acid encoding EBI-2 receptor or the encoded polypeptide are not supported by either a specific and substantial asserted utility or a well established utility, it follows that antibodies that bind said receptor and methods of producing said antibody also not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above

7. Claims 23-74 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the EBI-2 receptor and antibody that bind said EBI-2, further experimentation is necessary to attribute a utility to the claimed antibody and methods for it production.

Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Further claims 39, 50, 65, 74 are rejected because the immunogen introduced into an animal to produce an antibody or antibody fragment that binds to the polypeptide of SEQ ID NO:2 is not disclosed. The term "immunogen" carries no weight in terms of structure and function and

encompasses an unlimited number of alterations and reads on unrelated molecules. The specification discloses the polypeptide of SEQ ID NO:2. Although the polypeptide of SEQ ID NO:2 can be used as an immunogen to produce antibody which specifically binds to the polypeptide of SEQ ID NO:2, by introducing said polypeptide into an animal as an immunogen, no other immunogens are disclosed that can be used to produce an antibody which specifically binds to the polypeptide of SEQ ID NO:2. The critical feature of the immunogen, when introduced into an animal that causes it to produce antibody that specifically binds to the polypeptide of SEQ ID NO:2 is not disclosed. Also, claims 50 and 74 are rejected because the method of preparing an antibody fragment, contains the same steps as those used to produce an intact antibody, but with the outcome the fragment is isolated. There is no disclosure in the prior art that antibody fragments,. i.e. Fab and single chains can be naturally produced and recovered. The specification nor prior art provide any guidance as to which immunogen apart from the polypeptide of SEQ ID NO:2 can be used to produce an antibody that specifically bind to said polypeptide. The specification does not teach how to make, identify or isolate a commensurate number of immunogens encompassed by the claims. Therefore one must engage in case to case painstaking experimental study to determine which immunogens when introduced into an animal, that causes it to produce antibody that specifically binds to the polypeptide of SEQ ID NO:2. Consequently, excessive trial and error experimentation would have been required to identify the necessary immunogens.

As set forth in *In re Fisher,* 166 USPQ 18 (CCPA 1970), compliance with 35 USC 112, first paragraph requires:

that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.

In *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991), the court ruled that a claim to a large genus of possible genetic sequences encoding a protein with a particular function that needs to be determined subsequent to the construction of the genetic sequences may not find sufficient support under 35 USC 112, 1st para., if only a few of the sequences that meet the functional limitations of the claim are disclosed and if undue experimentation would be required of one skilled in the art for determining other genetic sequences embraced by the claim. This is the case here, where specification discloses only one amino acid sequence, SEQ ID NO:2, and provides no guidance on obtaining immunogens that can be used to produce antibody which specifically binds to the polypeptide of SEQ ID NO:2 by introducing said immunogen into an animal.

8. Claims 39, 65, 50 and 74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed immunogens, which

when introduced into an animal would produce the antibody that specifically binds to the polypeptide of SEQ ID NO:2.

Although the polypeptide of SEQ ID NO:2 can be used as an immunogen to produce antibody which specifically binds to the polypeptide of SEQ ID NO:2, by introducing said polypeptide into an animal as an immunogen, no other immunogens are disclosed that can be used to produce an antibody which specifically binds to the polypeptide of SEQ ID NO:2. The critical feature of the immunogen, when introduced into an animal that causes it to produce antibody that specifically binds to the polypeptide of SEQ ID NO:2 is not disclosed. As discussed, in detail, in the 35 USC § 112, 1st paragraph, enablement, rejection above, one must engage in case to case painstaking experimental study to determine the immunogens encompassed by the claims. Consequently, excessive trial and error experimentation would have been required to identify the necessary immunogens. The claims, due to the use of immunogen, encompass compounds completely unrelated to the polypeptide of SEQ ID NO:2. The instant disclosure of a polynucleotide of SEQ ID NO:2 does not adequately describe the scope of the use of the claimed genus of immunogens, which may encompasses a substantial wide variety of compounds. A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of compounds, eg polypeptides, defined by structure, eg. amino acid sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide

sufficient descriptive information, such as definitive structural or functional features of the claimed genus of immunogens. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the immunogens encompassed by the claim. No identifying characteristic or property of the instant immunogen that retains the biological activity is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly used to produce the claimed antibody. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of the ability to produce an antibody and the ability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

An adequate written description of an immunogen, requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention. Accordingly, an adequate written description of an immunogen is more than a mere statement that it is part of the invention and reference to a potential method for isolating

it; what is required is a description of the protein itself. Accordingly, the specification does not provide a written description for the "immunogen" of claims 39, 50, 65 and 74.

9. Claims 51-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

The deposit of biological material is considered by the Examiner to be necessary for the enablement of the current invention because the claims require availability of the deposit. The deposit of cDNA of ATCC Deposit No. 209003 is not in full compliance with 37 CFR §§ 1.803-1.809 because the specification does not provide a repeatable method for obtaining ATCC deposit and it does not appear to be a readily available material. Further, Applicant must provide evidence that deposited material will be available under the criteria (I)-(V) listed on page 4 of the Office Action. Although, the aforementioned deposit, if available today from ATCC, may not be available in the future. An enabled ATCC deposit would satisfy the requirements of 35 USC §112, first paragraph.

10. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
February 3, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600